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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,302	07/17/2003	Anders Bendtz Kanstrup	6197.214-US	2223
23650	7590	01/03/2006	EXAMINER	
NOVO NORDISK, INC. PATENT DEPARTMENT 100 COLLEGE ROAD WEST PRINCETON, NJ 08540			BERCH, MARK L	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/621,302	KANSTRUP ET AL.
	Examiner	Art Unit
	Mark L. Berch	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 November 2005.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1 and 2 is/are rejected.

7) Claim(s) 3-10 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 11/18/05.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 103***

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

**Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romanenko.**

See compounds IX and XX in the translation. These species are taught as diuretics; X is in fact named as a particularly potent drug. These species,.. Which have 7-heptyl and 7-(3-Cl-but-2-enyl) are excluded by the 5<sup>th</sup> and 6<sup>th</sup> from last provisos and hence the reference is not an anticipation.

However, the 7-nonyl derivative would be an obvious variant of these two species. 7-nonyl is seen in X and XI, two of the more potent species. It is noted that X, with nonyl, is more potent than VI, with the heptyl, thus giving one of ordinary skill in the art the motivation to use nonyl rather than heptyl.

Alternatively, XI and X themselves render the claims obvious. These differ only in that these have the 8-morpholino and 8-piperidino rather than the 8-piperazino of the claims. However, since all three rings are taught by the reference, it is clear what the piperazine ring (which appears in XX, one of the most potent species) is alternatively useable for the purposes of the invention, and hence is an obvious variation.

The traverse is unpersuasive. Applicants have cited *In re Dance* 48 USPQ2d 1635.

This case dealt with the situation where two references were being combined, and dealt with a situation where non-obviousness was asserted on the basis that one of the references "teaches away" from the desired modification. Neither of these applies here.

Applicants have cited *In re Kotzab* 55 USPQ2d 1313. This case turned on the fact that the reference did not teach or suggest the use of a single temperature sensor. The reference instead had "one system", and there was no evidence in the record that would equate "one system" with "one sensor." This was a case turning on the very specific facts involved, and seems to have no relationship to the facts here.

Applicants have cited *In re Deminski* 230 USPQ 313. There, the Court held that labeling a key feature as a "common practice" constituted a "hindsight analysis". The examiner in this case has made no such resort, instead referring only to things which are precisely in the reference.

Applicants have cited *B.F. Goodrich Co. v. Aircraft Braking Systems Corp.* 37 USPQ2d 1314. In that case, which was not a chemical case, the Court held that secondary considerations are were not convincing of nonobviousness in view of minor difference between claimed invention and teachings of reference. It is not seen what this has to do with the issues at hand.

Applicants have cited *In re Grabiak*, but that case dealt with the difference between O and S, not relevant here.

Applicants state that the examiner is "reading into the art what applicant teaches." The examiner is not. The critical pieces, the heptyl group and the piperazinyl group, are explicitly taught by the reference, and the only the only reason that the reference is not a

102 altogether is that these two do not appear in the same individual species. There is however plenty of motivation to use these groups for reasons set forth above.

Lastly, applicants point to a difference in utility, and cite a 1968 Board of Appeals decision. This decision has been superceded by later ones. The fact that the prior art compounds are not disclosed to have this property is not enough to avoid an obviousness rejection. Applicants must show that the prior art compounds do not actually have the property disclosed here, by suitable comparative testing. Cf *In re Dillon*, 16 USPQ2nd 1897, 1901; *In re Hoch*, 166 USPQ 406; *Brown v. Gottshalk*, 179 USPQ 65; *In re Murch*, 175 USPQ 430. Note also *In re Lintner*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). It is not necessary for the prior art to have recognition or appreciation of this activity for other than method of use claims. See also *In re Shetty*, 195 USPQ 753 for a case where the prior art did not teach applicants' exact utility. Note also *In re Baxter Travenol Labs*, 21 USPQ2d 1281, 1285 which states, "Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention." Note also *In re Ona*, 38 USPQ2d 1597 ("...all benefits need not be explicitly disclosed to render the claims unpatentable..."). See MPEP 2144 and 2145.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The original "heteroaryl C1-C3 alkyl" choice for R1 (third from last) was unclear. Is a) the heteroaryl a substituent on an alkylene or b) is the heteroaryl part of the chain itself, i.e. -Heteroaryl-alk-? In response, applicants amended to claim language to read "heteroaryl C1-C3 alkylene", which constitutes selection of the a) choice. However, the remarks state that the heteroaryl is "part of the chain itself", which is actually the b) choice.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The selection made above, that is, the ring is part of the chain itself, lacks description in the specification. Applicants need to show how one of ordinary skill in the art would have been able to figure out that this choice, (i.e. b)) was intended. Applicants have not done this. They simply say that it "would be clear" without giving reasons.

Claims 3-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed

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until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch  
Primary Examiner  
Art Unit 1624

12/27/05